§ 813.12 Information previously submitted.

Wherever this part requires the submission to the Food and Drug Administration of information or data that previously had been submitted in accordance with this part or other parts of this chapter, the information or data need not be resubmitted but may be incorporated by reference.

§ 813.19 Requirements applicable to importers and exporters of intraocular lenses.

(a) Any person who imports or offers for importation into the United States an intraocular lens shall assure that all the following requirements are met:

(1) The labeling of such lens complies with §813.5 (a) and (b).

(2) The importer of such shipment is an agent in the United States of the foreign exporter or is the ultimate consignee, and the foreign exporter or the ultimate consignee has, prior to such shipment, completed and submitted to the Food and Drug Administration an application for an investigational device exemption in accordance with §813.20 and acts as the sponsor of the investigational study to assure compliance with the procedures, conditions, and requirements of this part.

(3) The requisite time has elapsed after the date of receipt of the application by the Food and Drug Administration to permit the investigational study to begin under §813.30(b).

(4) The Commissioner has not disapproved the application or withdrawn the exemption.

(b) Any person who exports an intraocular lens from the United States to a foreign country shall comply with all the following requirements:

(1) The lens shall conform to the specifications of the foreign purchaser.

(2) The lens shall comply with the laws of the country to which it is being exported.

(3) The label on the outside of the shipping package shall indicate that the lens is intended for export.

(4) The lens shall not be sold or offered for sale in domestic commerce.

(5) The person shall obtain the approval of the exportation of the lens from the country to which it is intended for export.

(6) The person shall request and obtain from the Commissioner a determination that the exportation of the device is not contrary to the public health and safety and has the approval of the country to which it is intended for export.

Subpart B—Applications for Exemption for Investigational Studies Involving Human Subjects

§ 813.20 Application.

(a) The sponsor of an investigational study shall submit to the Food and Drug Administration a completed application for an investigational device exemption that has been signed by the sponsor or an authorized representative of the sponsor. Three copies of the application and any material required to accompany the application, bound and contained in volumes of reasonable size, shall be sent by registered mail or hand delivered to the Center for Devices and Radiological Health Document Mail Center (HFZ–401), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850. Any subsequent reports, correspondence concerning an application, and supplemental application submitted under §813.39 also shall be submitted in triplicate by registered mail or hand delivered to this address. The outside wrapper of any application or supplemental application should include the statement ''Application (or Supplemental Application) for Investigational Device Exemption'' and the outside wrapper of any reports or correspondence should include the statement, ''Regarding an Investigational Device Exemption''.

(b) An application for an investigational device exemption for an intraocular lens shall include the following information:

(1) A brief statement of its intended use(s) and how it is to be administered.

(2) A description of all components, ingredients, and properties and a description of the principle of operation of the device and any anticipated changes in the device that may occur in the course of the study in enough detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about

the anticipated safety and effectiveness of the lens in the proposed investigational study.

(3) A description of those methods, facilities, and controls, used for the manufacture, processing, packing, and storage of the device in enough detail so that a person generally informed in that area can make a knowledgeable judgment about the safety and effectiveness of the device in the proposed investigational study.

(4) A statement of the location(s) of the study and whether an institutional review committee(s) is to monitor the study at such location(s).

(5) A report of prior investigations of the device that meets the requirements of §813.27 and a summary of the investigational plan.

(6)(i) A statement from the sponsor that an investigational plan that meets the requirements of §813.25 and a report of prior investigations of the device that meets the requirements of §813.27 have been submitted to and approved by the institutional review committee, or (ii) if no institutional review committee exists and one cannot be formed, a statement from the head of the institution that such a committee cannot be formed, and copies of the investigational plan and the report of prior investigations.

(7) A statement from any institutional review committee (where a committee is to monitor the study), signed by the chairman, that the committee has approved the investigational plan and has reviewed the report of prior investigations of the lens, that the committee will review the study periodically at intervals appropriate to the degree of risk but not to exceed 1 year, and that it will review reports of unexpected adverse effects on a timely basis for the purpose of determining if the study should be continued.

(8) A copy of all informational materials to be given to subjects, including all form(s) to be used to obtain informed consent of human subjects as required by Part 50 of this chapter (this material may be appended to the investigational plan or the summary of the investigational plan).

(9) A copy of all informational material, including labels and other labeling, which is to be supplied to investigators as required by §813.47(a).

(10) A description of the scientific training and experience that the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See §813.43(a).)

(11) A copy of the agreement signed by investigators who will be participating, to comply with Subparts E and G of this part and Part 50 of this chapter as required by §813.43(b).

(12) The name and a summary of the training and experience of the individual who is to monitor the progress of the study for the sponsor as required by Subpart C.

(13) A statement as to whether any institutional review committee has ever disapproved any investigational study of the device and the reasons for such disapproval.

(14) A statement that the sponsor will comply with each of the requirements of Subparts C and G of this part.

(15) A statement by a sponsor notifying FDA if he intends to charge investigators and subjects for the device.

(16) A statement by the sponsor of his reasons for any request for a waiver of the requirement of §813.30(a) that a study shall not begin before the expiration of 30 days after the Food and Drug Administration has received an application meeting the requirements of this subpart, if such waiver is requested.

(17) A claim for categorical exclusion under §25.24 of this chapter or an environmental assessment under §25.31 of this chapter.

(18) Any other information relevant to review of the application required by the Food and Drug Administration to be submitted. The sponsor may refuse to provide the information requested under paragraph (b)(18) of this section and treat FDA's request as a final disapproval for purposes of requesting a regulatory hearing under §813.30. If a sponsor fails to respond to a request for information within the time prescribed in a request, FDA may treat the application as withdrawn.

[42 FR 58889, Nov. 11, 1977, as amended at 47 FR 46079, Oct. 15, 1982; 50 FR 16669, Apr. 26, 1985; 53 FR 11253, Apr. 6, 1988; 55 FR 11169, Mar. 27, 1990]

§ 813.25 Investigational plan.

(a) The investigational plan for the investigational study of an intraocular lens shall include the following:

(1) A statement of the intended use of the lens;

(2) A general outline of the plan and any anticipated or forseeable changes or variations in the plan that may be made based on experience gained in the study;

(3) A description of what results are expected from the investigational study;

(4) A justification for beginning the study, taking into account prior experience with the intraocular lens;

(5) the expected duration of the investigational study;

(6) Identification of the investigator or investigators, the facilities where the study will occur, and any institutional review committees that will supervise the study;

(7) The patient population in which the lens will be used (in terms of age, sex, and condition) and the size of each population;

(8) A justification for using such patient population and of the size of each population;

(9) The sponsor's plan for monitoring the study in accordance with § 813.46;

(10) A description of records to be maintained, and the reports to be made, by the investigator(s) and the sponsor to assure compliance with the plan and enable the progress of the investigation and the safety and effectiveness of the lenses to be reviewed by the sponsor, any institutional review committee, and the Food and Drug Administration;

(11) The plan for obtaining informed consent from subjects and copies of all informational materials to be given to subjects, including all forms and materials to be used in obtaining such consent; and

(12) A description of the scientific training and experience the sponsor considers appropriate to qualify individuals as suitable experts to investigate the safety and effectiveness of the intraocular lens. (See § 813.43(a)).

(b) The procedures and conditions in the investigational plan may vary depending on the following:

(1) The scope and duration of the investigational study;

(2) The number of human subjects who are to be involved in the study;

(3) The need to permit changes to be made in the device during the study conducted in accordance with the plan; and

(4) The purpose of the study, e.g., whether the study is designed for developing data to obtain approval for the commercial distribution of the device.

(c) When an investigational study is to develop data to obtain approval for commercial distribution of the device, the Food and Drug Administration will not ordinarily regard an investigational plan as capable of providing data that will support an application for such approval unless it provides for more than one independent qualified investigator.

(d) The investigational plan may provide for additional animal tests to be made during the investigational study.

[42 FR 58889, Nov. 11, 1977; 43 FR 1940, Jan. 13, 1978]

§ 813.27 Report of prior experience with the lens.

(a) A report of prior investigations with the lens shall be submitted to an institutional review committee and to the Food and Drug Administration.

(b) The report of prior investigations of a lens shall include:

(1) A bibliography of any publications relevant to the investigational study and copies of significant publications both adverse and supporting.

(2) Any other unpublished information available to the sponsor, both adverse and supporting, information relating to preclinical investigations of the lens, including appropriate tests in animals and tests in vitro, and prior clinical investigations of the device or clinical experience with the device from commercial marketing, whether in the United States or in foreign countries, in sufficient detail so that a scientist or physician familiar with the general type of lens can make a knowledgeable judgment about the anticipated safety and effectiveness of the device in the proposed investigational study.